

REMARKS

Claims 1, 31, 32, 35-42, and 44-52 are pending. Claims 1, 41, 42, and 51 are objected to due to language informalities. Claims 1, 31, 32, 35-42, 45, 49, 50 and 52 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 41, 42, 44, 46-48, 50 and 51 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 1, 31, 32, 35-42, and 44-50 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting. Each of these issues is addressed below.

Amendments

Applicants have amended claims 1, 35, 39, 41-42, 44, 46, 48, and 50-51 for the sake of clarity. Claims 31 and 32 have been cancelled. Additionally, claims 43, 45, 49, and 52 have been cancelled, and their subject matter incorporated into independent claims 42, 44, 48, and 51, respectively. For the record, Applicants do not agree with the rejections raised in this case but wish to pursue the cancelled subject matter in a later continuation application and reserve the right to do so. These amendments add no new matter.

Claim Objections

Applicants have amended claim 1 to recite the abbreviations for adeno-associated virus (AAV) and adeno-associated virus 2 (AAV2).

Claims 41 and 51 have been amended to replace the term “method” with the term “process.”

Claim 42 has been amended to state that AAV2 “nucleic acid” encodes the mutated structural protein, and the misplaced preposition has been removed, as requested by the Examiner.

In view of these amendments, Applicants submit that claims 1, 41, 42, and 51, and their dependent claims, are now free of the recited claim objections.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 31, 32, 35-42, 45, 49, 50 and 52 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite and failing to distinctly claim the subject matter of the disclosed invention.

Independent claims 1, 41, 42, 48, and 51 have been amended to require that the mutated structural protein comprise “an insertion” of amino acids directly adjacent to and after the amino acid “N” in LQRGN RQAAT (SEQ ID NO: 7). As indicated by the Examiner, regardless of the number or nature of the amino acids inserted at that site, the insertion does occur at a single position.

Further, claims 1, 39, and 41 are amended to distinguish the relationship between the AAV and the structural protein in that infectivity of an AAV having the mutated structural protein is increased.

Finally, Applicants note that claims 31 and 32 are now canceled, and claim 40 now clarifies that the nucleic acid is the nucleic acid of claim 39, as requested by the Examiner.

The indefiniteness rejections may be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 41 and 42 stand further rejected as failing to comply with the written description requirement. Further, claims 41, 42, 44, 46-48, 50 and 51 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with enablement requirement.

Taking each rejection in turn, with respect to the written description rejection of claims 41 and 42, the Office acknowledges that the specification describes an insertion at amino acid 587 of SEQ ID NO:7 in AAV and that such an insertion results in particle formation and increased infectivity. Claims 41 and 42 have been amended to require that the mutated structural protein comprise an insertion of amino acids at that position.

Furthermore, claims 41 and 42 now recite that the insertion of amino acids occurs directly

adjacent to and after the amino acid “N” (amino acid 587) in LQRGN RQAAT (SEQ ID NO: 7). The written description rejection of claims 41 and 42 may be withdrawn.

With respect to the enablement rejection of claims 41, 42, 44, 46-48, 50, and 51, Applicants again refer the Examiner to the amendment of claims 41 and 42 and the Office’s acknowledgement that AAV structural proteins having an insertion at position 587 are enabled. Moreover, Applicants note that claim 44 has been amended to incorporate the subject matter of cancelled claim 45, claim 48 has been amended to incorporate the subject matter of cancelled claim 49, and claim 51 has been amended to incorporate the subject matter of cancelled claim 52. As cancelled claims 45, 49, and 52 were indicated by the Office to be enabled, Applicants submit that the currently amended claims 44, 48, and 51, and their dependent or related claims 46, 47, and 50, are enabled as well.

Applicants further note that, contrary to the statement by the Office (see, e.g., p. 9, ¶ 1) that Applicants enable only insertions in VP3 because insertions at amino acid 587 occur in VP3, Applicants point out that an insertion at that site leads to an insertion in all three capsid proteins, VP1, VP2 and VP3, due to overlap in their coding sequences. This is highlighted in Wu et al. (of record) at Figure 1, in combination with the specification (see, e.g., p.2, ll. 3-6) that teaches the overlapping reading frames for the three AAV capsid proteins. In Figure 1 of Wu et al., VPN1 denotes the N-terminus at location 1, VPN2, the N-terminus at location 138, and VPN3, the N-terminus at location 203. Thus, the described amino acid insertion at 587 clearly occurs in all three AAV capsid proteins and demonstrates enablement for the VP1, VP2, and VP3 structural proteins, as required by the current claims.

The § 112, first paragraph rejections should be withdrawn.

Obviousness-Type Double Patenting

Claims 1, 31, 32, 35-42, and 44-50 stand further provisionally rejected under the

judicially created doctrine of obviousness-type double patenting over claims 121, 122, 130, and 143 of co-pending Application No. 10/498,163. Applicants wish to defer response to this rejection until such time as allowable subject matter in the '163 application and otherwise allowable subject matter in the present case have been indicated.

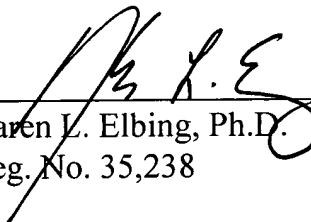
CONCLUSION

Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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